



Attorney Docket No. GENE-078/06US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MENDRICK *et al.*

Confirmation No.: 1420

Serial No.: 10/541,937

Group Art Unit: 1635

Filed: July 10, 2006

Examiner: Unassigned

For: MOLECULAR CARDIOTOXICOLOGY MODELING

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Enclosed is an Information Disclosure Statement and accompanying Form PTO/SB/08 for the above-identified patent application.

- ☐ In accordance with 37 C.F.R. §1.97(c), also enclosed is:
- ☐ the fee of \$180.00 as set forth in 37 C.F.R. §1.17(p); or
 - ☐ a statement as specified in 37 C.F.R. §1.97(e).
- ☒ A return receipt postcard is also enclosed.
- ☐ Please charge \$180.00 to Deposit Account No. 50-1283 for the total fee. This paper is being submitted in duplicate.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

Respectfully submitted,
COOLEY GODWARD LLP

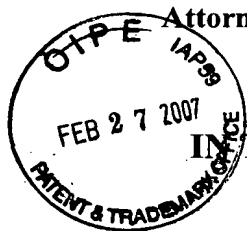
Dated: February 27, 2007

COOLEY GODWARD LLP
ATTN: Patent Group
The Bowen Building
875 15th Street NW, Suite 800
Washington, DC 20005-2221
Tel: (202) 842-7800
Fax: (202) 842-7899

By:

Hong Liu for
(Hong Liu, Reg. # 54,891)
Michael S. Tuscan
Reg. No. 43,210

34



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MENDRICK *et al.*

Confirmation No.: 1420

Serial No.: 10/541,937

Group Art Unit: 1635

Filed: July 10, 2006

Examiner: Unassigned

For: MOLECULAR CARDIOTOXICOLOGY MODELING

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(c)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- ☒ No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- ☒ The present application and its related applications generally disclose toxicology modeling of various tissues or cells, *e.g.*, heart, kidney, liver, or primary hepatocytes using gene expression data. As such, some of the nucleic acid sequences disclosed in this application may overlap with those disclosed in other related applications. For the Examiner's convenience, a list of the co-pending applications is presented below.

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
09/917,800	Molecular Toxicology Modeling	July 31, 2001	Liver

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
10/501,933	Molecular Hepatotoxicology Modeling	Jan. 31, 2003	Liver
11/059,535	Molecular Toxicology Modeling	Feb. 17, 2005	Liver
10/152,319	Molecular Toxicology Modeling	May 22, 2002	Kidney
10/515,325	Molecular Nephrotoxicology Modeling	Nov. 24, 2003	Kidney
11/036,196	Molecular Toxicology Modeling	Jan. 18, 2005	Kidney
11/642,647	Molecular Nephrotoxicology Modeling	Dec. 21, 2006	Kidney
10/338,044	Molecular Cardiotoxicology Modeling	Jan. 8, 2003	Heart
10/541,937	Molecular Cardiotoxicology Modeling	Jan. 8, 2004	Heart
11/600,759	Cardiotoxin Molecular Toxicology Modeling	Nov. 17, 2006	Heart
10/357,507	Primary Rat Hepatocyte Toxicology Modeling	Feb. 4, 2003	Hepatocyte
10/515,373	Primary Rat Hepatocyte Toxicity Modeling	Aug. 9, 2004	Hepatocyte
10/580,423	Methods For Molecular Toxicology Modeling	Nov. 24, 2004	General
11/547,759	Hepatotoxicity Molecular Models	Apr. 7, 2005	Liver

[X] In particular, the following publications were cited by the U.S. Patent Examiner in U.S. application 09/917,800:

1. U.S. 5,811,231
2. U.S. 6,372,431
3. U.S. 6,218,122
4. Lashkari *et al.* PNAS, vol. 94: 13057-13062, 1997

[X] The following publications were cited by the Examiner in U.S. application 10/152,319:

1. "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at <http://www.m-w.com/cgi-bin/dictionary?Book=Dictionary&va=nephrotoxic>
2. Yamaki *et al.* Cellular mechanism of lithium-induced nephrogenic diabetes insipidus in rats. American Journal of Physiology Renal Physiology, 1991. Vol. 261, F505-F511

[X] The following publication was cited by the Examiner in U.S. application 10/301,856:

1. Konstandi *et al.* Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catecholamines, 2004 Chemico-Biological Interactions, vol. 147

[X] The following publication was cited by the Examiner in U.S. application 10/191,803:

U.S. 6,461,807

[X] The following publications were cited by the Examiner in U.S. application 10/357,507:

1. U.S. 6,203,987
2. Peng *et al.* JBC, 271(6):3324-3327
3. GenBank Acc. No. AA799479 (4/30/1998)
4. GenBank Acc. No. AI177366 (1/20/1999)
5. GenBank Acc. No. M25823 (4/27/1993)
6. GenBank Acc. No. AA891812 (1/25/1999)

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US01/23872.

1. Raburn *et al.*, "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," Endocrinology 136(12):5769 - 5777, 1995
2. GenBank Accession No. L26268, Raburn *et al.*, "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996
3. Bissig *et al.*, "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol. Chem 269(4):3017-3021, 1994

4. GenBank Accession No. L23413, Bissig *et al.*, "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994
5. WO 00/12760
6. Farr *et al.*, "Concise review: gene expression applied to toxicology," *Toxicol Sci* 50(1):1-9, 1999
7. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153 - 159, 1999

[X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US02/21735.

1. US 2001/0039006 A1
2. US 2002/0119462 A1
3. Grigg *et al.* Environmental Health Institute to use gene chips to evaluate chemicals for potential harm to humans. NIEHS, 29 February 2000
4. US 6,228,589

[X] The following publications were cited in a foreign search or examination report corresponding to EP 01959321.9.

1. Markovich *et al.*, "Heavy metals mercury, cadmium, and chromium inhibit the activity of the mammalian liver and kidney sulfate transporter sat-1," *Toxicol. Appl. Pharmacol.* 154:181-187 (1999)
2. WO 99/58670
3. WO 93/01205
4. WO 99/43345
5. Berbner *et al.*, "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (*Onchorhynchus mykiss*) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," *Biomarkers* 4: 214-228 (1999)
6. Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," *Biochem. J.* 336:471-481 (1998)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/03194:

1. U.S. 6,218,122
2. U.S. 2001/0049139

[X] The following publications were cited in a foreign search or examination report corresponding to Canadian application 2,447,357

1. WO 01/32928, 05/11/01, Far *et al.*
2. Fielden *et al.* Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, *Toxicol. Sci.* 60: 6-10
3. Affymetrix Rat Toxicology U34 Datasheet, released 08/99

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02771863.4

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US02/16173:

1. U.S. 6,228,589
2. U.S. 6,365,352
3. U.S. 6,403,778
4. Kim *et al.*, Fumonisin B1 induces apoptosis in LLC-PK1 renal epithelial cells via a sphinganine and calmodulin dependent pathway. *Toxicology and Applied Pharmacology* 176:118-126 (2001)

5. Yang *et al.*, Differential regulation of COX-2 expression in the kidney by lipopolysacc: role of CD14. *Am J Physiology* 277(1):F10-F16 (1999)
6. Pfeffer *et al.*, Xanthine dehydrogenase and xanthine oxidase activity and gene expression in renal epithelial cells. *J Immunology* 153(4):1789-1797 (1994)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/37556:

1. U.S. Publication 2002/0142284, 10/03/2002, Raha *et al*
2. WO 94/17208
3. WO 97/13877

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02806804.7

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/025646:

1. Wilson, *et al.* Exploring drug-induced alterations in gene expression in mycobacterium tuberculosis by microarray hybridization. PNAS 96:12833-12838 (1999)
2. Tao, *et al.*, Profiling of differently expressed apoptosis-related genes by cDNA arrays in human cord blood DC34+ cells treated with etoposide. Experimental Dermatology, 31:251-2606 (2003)
3. Cadet, *et al.*, Distinct gene expression signatures in the striata of wild-type and heterozygous c-fos knockout mice following methamphetamine administration, Synapse, 44:211-2268 (2002)
4. He *et al.*, Histone deacetylase inhibitors induce remission in transgenic models of therapy-resistant acute promyelocytic leukemia., J. Biol. Chem., 276: 20858-20865 (2001)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/039593:

1. U.S. Publication 2003/0124552, 07/03/2003, Lindemann *et al*
2. U.S. 6,132,969, 02/17/2000, Stoughton *et al.*
3. U.S. 2003/0154032, 08/14/2003, Pittman *et al.*
4. U.S. 2003/0028327, 02/06/2003, Brunner *et al.*
5. Hasegawa *et al.* Gan To Kagaku Ryoho 30: 325-33 (abstract)

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/034780:

1. Boorman *et al.*, "Toxicogenomics, Drug Discovery, and the Pathologist," Toxicologic Pathology 30(1):15-27 (2002).
2. Harris *et al.*, "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," Mutation Research 539:79-99 (2004).
3. Gooderham *et al.*, "Molecular and genetic toxicology of 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine (PhIP)," Mutation Research 506-507:91-99 (2001).
4. Hogstrand *et al.*, "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," Comparative Biochemistry and Physiology Part B 133:523-535 (2002).

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/011532:

1. Kikuchi *et al.* Gene expression and activities of protein phosphatases 1 alpha, 2A, 2C in hepatocarcinogenesis and regeneration after partial hepatectomy. Cancer detection and prevention. 1997 vol.21(1): 36-43
2. Frazier *et al.* Predictive toxicodynamics: empirical/mechanistic approaches. Toxicology in Vitro, 1997, vol. 11: 465-472
3. Irizarry *et al.* Summaries of Affymetrix Gene Chip probe level data. Nucleic Acids Research, 2003, vol. 31, page e15
4. U.S. 6,153,421
5. U.S. 6,421,612
6. U.S. 5,858,659
7. Jakubczak *et al.* An oncolytic adenovirus selective for retinoblastoma tumor suppressor protein pathway-defective tumors. Cancer Research, 2003 vol 63:1490-1499

This Information Disclosure Statement is filed after the period specified in 37 C.F.R. § 1.97(b), but before the mailing of:

- ☐ a final action under 37 C.F.R. §1.113;
- ☐ a notice of allowance under 37 C.F.R. §1.311; or
- ☐ an action that otherwise closes prosecution in this application.

In accordance with 37 C.F.R. §1.97(c) also enclosed is:

- ☐ Fee under 37 C.F.R. §1.17(p) in the amount of \$180.00; or
- ☐ Statement as specified in 37 C.F.R. §1.97(e):
 - ☐ Each item of information contained in the Information Disclosure Statement cited herein was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing date of the Information Disclosure Statement; or
 - ☐ No item of information contained in the Information Disclosure Statement submitted herewith was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, having made a reasonable inquiry, no item of information contained in the Information Disclosure

Statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing date of the Information Disclosure Statement.

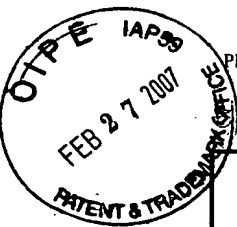
It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

Respectfully submitted,
COOLEY GODWARD LLP

Dated: February 27, 2007

COOLEY GODWARD LLP
ATTN: Patent Group
The Bowen Building
875 15th Street NW, Suite 800
Washington, DC 20005-2221
Tel: (202) 842-7800
Fax: (202) 842-7899

By: *Hong Liu for*
(Hong Liu, Reg. #54,891)
Michael S. Tuscan
Reg. No. 43,210



Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	1 of 24	Attorney Docket Number	GENE-078/06US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1.	5,811,231		Farr et al.	09-22-1998
	2.	5,858,659		Sapolsky et al.	01-12-1999
	3.	6,132,969		Stoughton et al.	02-17-2000
	4.	6,153,421		Yanagi et al.	11-28-2000
	5.	6,203,987		Friend et al.	03-20-2001
	6.	6,218,122		Friend et al.	04-17-2001
	7.	6,228,589		Brenner et al.	05-08-2001
	8.	6,365,352		Yerramilli et al.	04-2-2002
	9.	6,372,431		Cunningham et al.	04-16-2002
	10.	6,403,778		Cunningham et al.	06-11-2002
	11.	6,421,612		Agrafiotis et al.	07-16-2002
	12.	6,461,807		Friend et al.	10-8-2002
	13.	2001/0039006		Snodgrass	11-8-2001
	14.	2001/0049139		Lagasse et al.	12-6-2001
	15.	2002/0119462		Mendrick et al.	8-29-2002
	16.	2002/0142284		Raha et al.	11-3-2002
	17.	2003/0124552		Lindemann et al.	07-03-2003
	18.	2003/0154032		Pittman et al.	08-14-2003
	19.	2003/0028327		Brunner et al.	02-06-2003

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office	Number	Kind Code (if known)			
	20.	WO	93/01205		The Salk Institute for Biological Studies	1-21-1993	
	21.	WO	94/17208		Xenometrix, Inc.	4-08-1994	
	22.	WO	97/13877		Lynx Therapeutics, Inc.	04-17-1997	
	23.	WO	99/27090		Smithkline Beecham Corporation	06-03-1999	
	24.	WO	99/43345		Eisai Co., Ltd.; Beth Israel Deaconess Medical Center	09-02-1999	
	25.	WO	99/58670		Cadus Pharmaceuticals Corporation	11-18-1999	
	26.	WO	00/12760		Incyte Pharmaceuticals	9-3-2000	
	27.	WO	01/32928		Phase-I Molecular Toxicology	05-10-2001	
	28.	WO	01/25473		Source Precision Medicine, Inc.	04-12-2001	

Examiner Signature	Date Considered
-----------------------	--------------------

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →



Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
Examiner Name	Unassigned		
Sheet	2 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	29.	"nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at http://www.m-w.com/cgi-bin/dictionary?book=Dictionary&va=nephrotoxic , 2 pages
	30.	Aardema and MacGregor, Mutation Res., 499:13-25, (2002)
	31.	Adamson & Harman et al., Biochem. Pharmacol., 45: 2289-2294 (1993)
	32.	Affymetrix Rat Toxicology U34 Datasheet, released 08/99
	33.	Afshari et al., Cancer Res., 59: 4759-4760 (1999)
	34.	Agha et al., Lipid Peroxidation and Lysosomal Integrity ; 31., 279-285 (1995)
	35.	Ahotupa et al., Carcinogenesis., 15: 863-868 (1994)
	36.	Ala-Kokko, et al., Biochem. J., 244:75-79, (1987)
	37.	Al-Bayati & Stohs, Arch. Environ. Contam. Toxicol., 20: 361-365 (1991)
	38.	Allan et al., J. Biol. Chem., 276: 27272-27280 (2001)
	39.	Amelsen, Jean Claude., Setting death in motion , Vol., (1998)
	40.	Andersen & Barton, Environ. Health Perspect., 106: 349-355 (1998)
	41.	Anderson et al., Toxicol. Appl. Pharmacol., 137: 75-89 (1996)
	42.	Anderson, Steven P., Hepatic Expression of Acute-Phase Protein, 26: 226-238 (1999)
	43.	Andersson et al; Anthraquinone-induced cell injury; 135: 11-20 (1999)
	44.	Anton et al., Cell Biochem. Biophys., 32: 27-36 (2000) Abstract only
	45.	Arano et al ., Arzneim-Forsch./Drug, 46 : 398-400 (1996)
	46.	Atchison et al., Digestive Dis. Sci., 45: 614-620 (2000)
	47.	Bajgar et al., Neurochem. Int., 24: 555-558 (1994)
	48.	Baker et al., Chem. Res. Toxicol., 14(9): 1218-1231 (2001)
	49.	Bandara, et al., Toxicol. Sci., 73:195-206, (2003)
	50.	Barner & Gray, Ann. Pharmacother., 32: 70-77 (1998)

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →



PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
Examiner Name	Unassigned		
Sheet	3 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	51.	Bartosiewicz et al., J. Pharmacol. Exp. Ther., 297: 895-905 (2001)
	52.	Beck et al, Arch. Toxicol., 64: 210-217 (1990)
	53.	Becker et al., Alzheimer Dis. Assoc. Disord., 10: 124-131 (1996)
	54.	Bedard et al., Antimicrob. Agents Chemother., 43: 557-567 (1999)
	55.	Bedossa et al., Hepatology, 19: 1262-1271 (1994)
	56.	Beierschmitt, William P., Induction of Hepatic Microsomal Drug-Metabolizing,, 15-21
	57.	Belury et al., Toxicol. Appl. Pharmacol., 151: 254-261 (1998)
	58.	Berbner et al., "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (Onchorhynchus mykiss) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," Biomarkers 4: 214-228 (1999)
	59.	Bergeron et al., Xenobiotica, 28: 303-312 (1998)
	60.	Berndt et al., Proc. Natl. Acad. Sci. U.S.A., 95: 12556-12561 (1998)
	61.	Birge et al., Toxicol. Appl. Pharmacol., 105: 472-482 (1990)
	62.	Bissig et al., "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," J Biol Chem 269(4):3017-3021, 1994.
	63.	Boelsterli et al., Cell Biol. Toxicol., 3: 231-250 (1987)
	64.	Boess, et al., Toxicological Sciences, 73:386-402, (2003)
	65.	Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," Biochem. J. 336:471-481 (1998)
	66.	Boon, et al., Proc. Natl. Acad. Sci. USA, 99(17):11287-11292, (2002)
	67.	Boorman et al., "Toxicogenomics, Drug Discovery, and the Pathologist," Toxicologic Pathology 30(1):15-27 (2002).
	68.	Bort et al., J. Pharmacol. Exp. Ther., 288: 65-72 (1999)
	69.	Bosio and Borlak, Innovations in Pharmaceutical Technology, 65-75
	70.	Bouchard et al., Liver, 13: 193-202 (1993)
	71.	Bramow, Stephan, et al., Pharmacol. & Toxicol., 89:133-139, (2001)

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	4 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	72.	Browne, et al., Targets, 1(2):59-65, (2002)
	73.	Bruck et al., Dig. Dis. Sci., 44: 1228-1235 (1999)
	74.	Bulera, S.J., et al., Hepatology, 33:1239-1258, (2001)
	75.	Burchiel et al., Toxicol. Sci., 59: 193-195 (2001)
	76.	Burczynski & Penning, Cancer Res., 60: 908-915 (2000) Abstract only
	77.	Burczynski (Editor), "An Introduction to Toxicogenomics," Wyeth Research, Andover, MA, CRC Press pp. 226-259, (Pub. 2003)
	78.	Burczynski et al., Toxicol. Sci., 58: 399-415 (2000)
	79.	Burris, Hicken and Farr, Genetic Engineering News, 5/1/1999, pp. 42-43, (1999)
	80.	Bursch et al., Arch. Toxicol., 69: 253-258 (1995)
	81.	Buttar et al., Toxicology., 6: 9-20 (1976)
	82.	Butterworth et al., Cancer Res., 49: 1075-1084 (1989)
	83.	Cadet, et al., Synapset, 44:211-226 (2002)
	84.	Cai et al., J. Med. Chem., 41: 1970-1979 (1998)
	85.	Calabrese et al., J. Amer. College Toxicol., 15: 62-69 (1996)
	86.	Castell et al., Cell Biol. Toxicol., 13: 331-338 (1997)
	87.	Castle, A., et al., "Apex Necrosis," Soc. Of Tox. Mtg. (2004)
	88.	Castle, A., et al., "Effects of Multiple Cardiac Apex Necrosis Agents on Genome Wide Expression," Soc. Of Tox. Mtg. (2003) Abstract only
	89.	Castle, A.L., et al., "Liver Toxicity Prediction and Classification Using Microarray Data: . . .," Soc. Of Tox. Mtg., (2002)
	90.	Castle, Carver & Mendrick, Drug Disc. Today, 7(13):728-736, (2002)
	91.	Chan et al., Proc. Natl. Acad. Sci. U.S.A., 98: 4611-4616 (2001)
	92.	Chanda et al., Hepatology, 21: 477-486 (1995)
	93.	Chen et al., J. Biol. Chem., 275: 22619-22622 (2000)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	5 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	94.	Chen et al., J. Environ. Pathol. Toxicol. Oncol., 14: 83-99 (1995) Abstract only
	95.	Chen, et al., Mol. Carcinog. 30:79-87, (2001)
	96.	Chisholm et al., Am. J. Physiol., 276: G1165-G1173 (1999)
	97.	Chou et al., Proc. Natl. Acad. Sci. U.S.A., 98: 8113-8118 (2001)
	98.	Choudhary G., Human Health Perspectives on Environmental., 31 :1., 1-5
	99.	Christian et al., Toxicol. Appl. Pharmacol., 82: 239-255 (1986)
	100.	Clive et al., Fundam. Appl. Toxicol., 3: 587-602 (1983)
	101.	Coles et al., Arch. Biochem. Biophys., 264: 253-260 (1988)
	102.	Conforti et al., Agents Actions, 40: 176-180 (1993)
	103.	Coni et al., Hepatology, 17: 1109-1116 (1993)
	104.	Copenhagen et al., Journal of Hepatology; 30: 1 pg. (1999)
	105.	Corell et al., Acta Pharmacol. Toxicol. (Copenh), 45: 232-239 (1979)
	106.	Corton & Stauber, Toxicol. Sci., 58: 217-219 (2000)
	107.	Corton et al., Biochimie., 79: 151-162 (1997)
	108.	Corton et al., Cancer Lett., 134: 61-71 (1998)
	109.	Corton et al., Cancer Lett., 137: 9-15 (1999)
	110.	Corton et al., Mol. Pharmacol., 54: 463-473 (1998)
	111.	Cronin, M.T.D., IL Farmaco, 56:149-151, (2001)
	112.	Crosby et al., Toxicol. Appl. Pharmacol., 169: 205-221 (2000)
	113.	Cunningham et al., Ann. N.Y. Acad. Sci., 919: 52-67 (2000)
	114.	Cunningham, M.J., J. of Pharmacol. And Toxicol. Methods, 44:291-300, (2000)
	115.	Cutler, P., et al., Electrophoresis, 20:3647-3658, (1999)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	6 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	116.	D'Mello et al., Exp. Toxicol. Pathol., 51: 549-553 (1999)
	117.	Daniels, K., "Toxicogenomics: Database Construction, Predictive Modeling & Biomarker Discovery," U.S. Army - 7th Annual Health Protection Conf. (2004) Abstract only
	118.	Daniels, K., "Toxicogenomics: The Application of Gene Expression in Transforming Toxicology Screening," U.S. Army Center for Health Promotion & Preventive Medicine Seminar, (2004)
	119.	Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
	120.	Database Geneseq 'Online!', "Reverse transcription primer used in cDNA analysis technique," Database Accession No. AAQ75569, retrieved from EBI Accession No. GSN:AAQ75569 (1995)
	121.	Davila et al., Toxicology., 57: 267-286 (1989)
	122.	Davis et al., Cancer Res., 60: 2887-2891 (2000)
	123.	De Fabiani et al., J. Biol. Chem., 276: 30708-30716 (2001)
	124.	Del Giudice et al., IL Farmaco., 51: 693-698 (1996)
	125.	Delaney & Timbrell, Xenobiotica., 25: 1399-1410 (1995)
	126.	Demeule, Brossard and Beliveau, Am. J. Physiol. Renal Physiol. 277:F832-F840, (1999)
	127.	Diel et al., J. Steroid Biochem. Mol. Biol., 73: 1-10 (2000)
	128.	Diez-Fernandez, et al., Biochem. Pharmacol., 51:1159-1163, (1996)
	129.	Dodds & Rivory, Mol. Pharmacol., 56: 1346-1353 (1999)
	130.	Dos Santos et al., J. Am. Soc. Nephrol., 8: 361-367 (1997)
	131.	Duivenvoorden et al., Biochem. Biophys. Res. Commun., 215(2): 598-605 (1995)
	132.	Dutar et al., Brain Res., 527: 32-40 (1990)
	133.	Eadie et al., Med. Toxicol. Adverse Drug Exp., 3: 85-106 (1988)
	134.	Eikmans, et al., Kidney Int'l, 62:1125-1135, (2002)
	135.	Eldridge et al., Carcinogenesis, 11: 2245-2251 (1990)
	136.	Ellis & Isaacs, Cancer Res., 45: 6041-6050 (1985)
	137.	Emmison et al., Biochim. Biophys. Acta, 1083: 147-152 (1991)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	7 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	138.	Enomoto et al., Toxicol. Sci., 59: 169-177 (2001)
	139.	Evans & Relling, Science, 286:487-491, (1991)
	140.	Falzon et al., Br. J. Exp. Pathol., 66: 527-534 (1985)
	141.	Fan & Rozman, Toxicol. Lett., 75: 209-216 (1995)
	142.	Fan et al., J. Biol. Chem., 271: 24698-24710 (1996)
	143.	Farag & Hassib, Clin. Sci. (Lond), 84: 387-390 (1993)
	144.	Farghali et al., Methods Find. Exp. Clin. Pharmacol., 6: 449-454 (1984)
	145.	Farr & Dunn, Toxicol. Sci., 50: 1-9 (1999)
	146.	Farr et al., "Concise review: gene expression applied to toxicology," Toxicol Sci 50(1):1-9, 1999.
	147.	Fernandez-Tome & Sterin-Speziale, Pharmacology, 48: 341-348 (1994)
	148.	Ficazzola et al., Carcinogenesis, 22: 1271-1279 (2001)
	149.	Fielden & Zacharewski, Toxicol. Sci., 60: 6-10 (2001)
	150.	Fitten et al., J. Gerontol., 42: 681-685 (1987)
	151.	Forestier et al., Biochem. Biophys. Res. Commun., 225: 377-383 (1996)
	152.	Fracasso et al., Agents Actions, 22: 3-4 (1987)
	153.	Fracasso et al., Agents Actions, 31: 313-316 (1990)
	154.	Frazier JM, Predictive Toxicodynamics: Empirical/mechanistic approaches. Toxicology in Vitro, 1997. Pgs. 465-472, Vol. 11
	155.	Froesch et al., J. Biol. Chem., 274: 6469-6475 (1999)
	156.	Frueh et al., Mol. Pharmacol., 51: 363-399 (1997)
	157.	Fulgencio et al., Biochem. Pharmacol., 62: 439-446 (2001)
	158.	Furr, Ann. N.Y. Acad. Sci., 761: 79-96 (1995)
	159.	Furr, Eur. Urol., 29: 83-95 (1996)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	8 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	160.	Gallagher, et al., Toxicol. And Appl. Pharmacol. 134:81-91, (1995)
	161.	Ganem & Jefcoate, Toxicol. Appl. Pharmacol., 150: 68-75 (1998)
	162.	Garcia-Allan et al., J. Biochem. Mol. Toxicol., 14: 65-72 (2000)
	163.	Geiger et al., Agents Actions, 38: Spec No: C69-72 (1993) Abstract only
	164.	GenBank Accession No. AA799479 (04/30/1998)
	165.	GenBank Accession No. AA891812 (01/25/1999)
	166.	GenBank Accession No. AI177366 (01/20/1999)
	167.	GenBank Accession No. L23413, Bissig et al., "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994.
	168.	GenBank Accession No. L26268, Raburn et al., "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996
	169.	GenBank Accession No. M25823 (04/27/1993)
	170.	Genes on Clontech Atlas Human Stress/Toxicology Array from e-mail/ website dated 10/29/98
	171.	Gerhold et al., Physiol. Genomics, 5: 161-170 (2001)
	172.	Ghatineh & Timbrell, Biochem. Soc. Trans., 18: 1217-1218 (1990)
	173.	Ghatineh et al., Arch. Toxicol., 66: 660-668 (1992)
	174.	Gobe, G., et al., J. Am. Soc. Nephrol., 11:454-467, (2000)
	175.	Goll et al., Toxicol. Appl. Pharmacol., 160: 21-32 (1999)
	176.	Golub et al., "Molecular Classification of Cancer: Class Discovery and Class Prediction by gene Expression monitoring," Science 285:531-537 (1999)
	177.	Gombar et al. Assessment of Developmental Toxicity Potential of Chemicals by Quantitative Structure-Toxicity Relationship Models, Chemosphere, 1995, Vol. 31, No. 1, pgs. 2499-2510,
	178.	Gomez-Lechon, et al., Toxicol. Sciences, 65:299-308, (2002)
	179.	Gooderham et al., "Molecular and genetic toxicology of 2-amino-1-methyl-6-phenylimidazo[4,5-b]pyridine (PhIP)," Mutation Research 506-507:91-99 (2001)
	180.	Gram & Bentsen, Acta Neurol. Scand. Suppl., 97: 81-90 (1983)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	9 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	181.	Greaves et al., Cancer Res., 53: 3919-3924 (1993)
	182.	Green et al., Toxicol. Appl. Pharmacol., 76: 139-149 (1984)
	183.	GRIGG, Environmental Health Inst. to use gene chips to evaluate chemicals for potential harm to humans NEIHS, 29 Feb. 2000, entire document
	184.	Guardavaccaro et al., Mol. Cell. Biol., 20: 1797-1815 (2000)
	185.	Guarner et al., Liver, 5: 35-39 (1985) Abstract only
	186.	Hamada et al., Hepatology, 21: 1455-1464 (1995)
	187.	Hamada et al., J. Hepatol., 30: 807-818 (1999)
	188.	Hamadah, et al., Toxicol. Sciences, 67:232-240, (2002)
	189.	Hamaya, Y., et al., Anesth. Analg., 90:1177-1183, (2000)
	190.	Hargus et al., Chem. Res. Toxicol., 7: 575-582 (1994)
	191.	Hargus et al., Chem. Res. Toxicol., 8: 993-996 (1995)
	192.	Harries et al., Toxicol. In Vitro, 15: 399-405 (2001)
	193.	Harris et al., "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," Mutation Research 539:79-99 (2004)
	194.	Hartmann, et al., J. of Pharma. And Experim. Therap., 303:273-281, (2002)
	195.	Hartung & Wendel, Biochem. Pharmacol., 42: 1129-1135 (1991)
	196.	Hasegawa et al., Gan To Kagaku Ryoho 30:325-333 abstract (2003)
	197.	Hassett et al., Biochem. Pharmacol., 55: 1059-1069 (1998) Abstract only
	198.	Hayashi et al., Biochim. Biophys. Acta., 879: 140-148 (1986) Abstract only
	199.	He et al., J. Biol. Chem., 276: 20858-20865 (2001)
	200.	He, et al., J. Clin. Invest., 108: 1321-1330 (2001)
	201.	Hellriegel et al., Biochem. Pharmacol., 52: 1561-1568 (1996)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	10 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	202.	Henger and Kretzler, et al., Kidney Int'l, 65:904-917, (2004)
	203.	Hessel et al., Braz. J. Med. Biol. Res., 29: 793-796 (1996)
	204.	Hewitt, et al., J. Am. Soc. Nephrol. 15:1677-1689, (2004) Abstract only
	205.	Higgs, B., et al., "Effects of Rat Gender and Strain on Elucidating Liver Toxicity," Soc. Of Tox. Mtg., (2003) Abstract only
	206.	Hildebrand et al., Arch. Toxicol., 73: 233-245 (1999) Abstract only
	207.	Hillstrom et al., Proc. Soc. Exp. Biol. Med., 200: 122-126
	208.	Hissink et al., Chem. Res. Toxicol., 9: 1249-1256 (1996)
	209.	Hoebe et al., Vet. Q., 22: 21-25 (2000) Abstract only
	210.	Hogstrand et al., "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," Comparative Biochemistry and Physiology Part B 133:523-535 (2002)
	211.	Hogue, Chemical and Engineering News, 79: 33-34 (2001)
	212.	Hoshi et al., Jpn. J. Pharmacol., 50: 289-293 (1989)
	213.	Huang, et al., Toxicol. Sciences, 63:196-207, (2001)
	214.	Hunter et al., Br. J. Pharmacol., 98: 79-86 (1989)
	215.	Hwang, et al., Biochem. And Biophys. Res. Commun., 146(I):87-93, (1987)
	216.	Iida, et al., Carcinogenesis, 24(4):757-770, (2003)
	217.	Inohara et al., EMBO J., 17: 2526-2533 (1998)
	218.	International Search Report in Applicant's corresponding PCT application, WO 02/095000 A3, published Nov. 28, 2002
	219.	International Search Report in Applicants' PCT Application No. PCT/US01/23872, March 21, 2003.
	220.	International Search Report in Applicants' PCT Application No. PCT/US05/34780, March 30, 2006.
	221.	International Search Report in Applicants' PCT Application No. PCT/US04/39593, March 8, 2006.
	222.	International Search Report in Applicants' PCT Application No. PCT/US05/11532, mailed September 13, 2006.

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	11 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	223.	Iredale et al., J. Clin. Invest., 102: 538-549 (1998)
	224.	Irizarry et al. (2003), "Summaries of Affymetrix GeneChip probe level data," Nucl Acids Res 31(4):e15, 8 pp.
	225.	Iswaran et al., J. Toxicol. Sci., 22 75-88 (1997)
	226.	Itoh et al., Behav. Brain Res., 83: 165-167 (1997)
	227.	Itoh et al., Eur. J. Pharmacol., 322: 11-19 (1997)
	228.	Izumi et al., J. Biol. Chem., 272: 7381-7389 (1997)
	229.	Jaeschke, et al., Toxicol. Sciences, 65:166-176 (2002)
	230.	Jakubczak et al., An Oncolytic Adenovirus Selective for Retinoblastoma Tumor Suppressor Protein Pathway-Defective Tumors, Cancer Research, April 1, 2003, Vol. 63, pgs. 1490-1499
	231.	Jansen, Muller, and Sturm, Hepatology, 34(6):1067-1074 (2001)
	232.	Jean et al., Toxicol. Lett., 95: 155-163 (1998)
	233.	Jenner & Timbrell, Arch. Toxicol., 68: 349-357 (1994)
	234.	Jeon et al., Toxicol. Appl. Pharmacol., 144: 27-35 (1997)
	235.	Johnson and McMillian, 23rd Annual Mtg. Of the Amer. College of Toxicology, p.532 (2002)
	236.	Johnson and Wolfgang, Current Topics in Med. Chem., 1(4):233-245, (2001)
	237.	Johnson, K., et al., "Predictive Modeling of Hepatotoxicants Using Microarrays and a Linear Discriminant Modeling Approach," ISMB Conf., August 2002, (2002)
	238.	Johnston & Kroening, Pharmacol. Toxicol., 83: 231-239 (1998)
	239.	Jover et al., Toxic. in Vitro., 6: 47-52 (1992)
	240.	Kanaji et al., J. Cell Biol., 151: 277-288 (2000)
	241.	Kannan et al., Oncogene., 20: 2225-2234 (2001)
	242.	Karam & Ghanayem, Carcinogenesis, 18: 2077-2083 (1997)
	243.	Kasper & Mueller, Carcinogenesis, 17: 2271-2274 (1996)
	244.	Kawamoto, et al., Gene, 174:151-158 (1996)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	12 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	245.	Kesterson et al., Hepatology, 4: 1143-1152 (1984)
	246.	Kikuchi et al., Gene Expressions and Activities of Protein Phosphatases 1 alpha, 2A and 2C in Hepatocarcinogenesis and Regeneration After Partial Hepatectomy, Cancer Detection and Prevention, 1997, Vol. 21(1), pgs. 36-43
	247.	Kim & Ziegler, Drug Metab. Dispos., 28: 1003-1006 (2000)
	248.	Kim et al., Drug Metab. Dispos., 26: 66-72 (1998)
	249.	Kim et al., Toxicol. Appl. Pharmacol., 102: 34-39 (1990)
	250.	Kim et al., Toxicology and Applied Pharmacology 176:118-126 (2001)
	251.	Kinbara et al., Scand. J. Gastroenterol., 32: 947-952 (1997)
	252.	Kingsley et al., Epilepsia, 21: 699-704 (1980)
	253.	Kingsley et al., J. Clin. Pharmacol., 23: 178-185 (1983)
	254.	Knapp et al., Am. J. Vet. Res., 56: 801-805 (1995)
	255.	Kocarek et al., Mol. Pharmacol., 54: 474-84 (1998)
	256.	Koga et al., Fukuoka Igaku Zasshi, 82: 197-206 (1991)
	257.	Kondo et al., Cancer Res., 50: 6222-6228 (1990)
	258.	Kongo et al., Toxicol. Lett., 105: 103-110 (1999)
	259.	Konstandi et al., "Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catecholamines," Chemico-Biological Interactions 147:abstract, (2004)
	260.	Koopen et al., Hepatology 27: 537-545 (1998)
	261.	Koopen et al., J. Lipid. Res., 40: 100-108 (1999)
	262.	Kossor et al., Biochem. Pharmacol., 46: 2061-2066 (1993)
	263.	Kossor et al., Fundam. Appl. Toxicol., 26: 51-62 (1995)
	264.	Kossor et al., Toxicol. Appl. Pharmacol., 119: 108-114 (1993)
	265.	Kretz-Rommel & Boelsterli, Toxicol. Appl. Pharmacol., 120: 155-161 (1993)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box ➡ +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	13 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	266.	Kurota and Yamaguchi, Molec. And Cell. Biochem., 151:55-60, (1995)
	267.	Kwak et al., Mol. Med., 7: 135-145 (2001)
	268.	Kwon, et al., Am. J. Physiol. Renal Physiol. 279:F552-F564, (2000)
	269.	Lake et al., Toxicology., 131: 9-20 (1998)
	270.	Lake et al., Hepatic Effects of Phthalate Esters and Related., 67: pp. 283-290, (1986)
	271.	Lake, Annu. Rev. Pharmacol. Toxicol., 35: 483-507 (1995).
	272.	Lang et al., Alcohol Clin. Exp. Res., 22: 823-829 (1998)
	273.	Larsen & Jefcoate, Arch. Biochem. Biophys., 321: 467-476 (1995)
	274.	Lashkari et al., PNAS 94:13057-13062, (1997)
	275.	Laskin et al., Hepatology, 21: 1045-1050 (1995)
	276.	Lauredo et al., J. Appl. Physiol., 85: 2298-2304 (1998)
	277.	Lazartigues et al., Eur. J. Pharmacol., 361: 61-71 (1998)
	278.	LeBlank, G., et al., Cancer Research, 52:540-547, (1992)
	279.	Lecureur, V., et al., Toxicology, 153:203-219, (2000)
	280.	Lee et al., J. Pharm. Pharmacol., 52: 341-355 (2000)
	281.	Lees et al., Lipids, 30: 221-226 (1995)
	282.	Leifeld, et al., Amer. J. of Pathol., 154(6):1711-1720, (1999)
	283.	Lewis et al., Hepatology, 2: 870-873 (1982)
	284.	Li et al., Zhonghua Gan Zang Bing Za Zhi, 9: 103-104 (2001)
	285.	Liang et al., Zhonghua Gan Zang Bing Za Zhi, 7: 72-73 (1999)
	286.	Liu et al., Infect. Immun., 66: 5089-5098 (1998)
	287.	Liu et al., Mol. Cell. Biol., 20: 6105-6113 (2000)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box ➔ +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	14 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	288.	Liu et al., Proc. Natl. Acad. Sci. U.S.A., 98: 6192-6197 (2001)
	289.	Liu et al., SHOCK, 14: 361-365 (2000)
	290.	Lock et al., Toxicol. Lett., 10: 427-435 (1982)
	291.	Lorenzini et al., Carcinogenesis, 17: 1323-1329 (1996)
	292.	Lovett, Science, 289: 536-537 (2000)
	293.	Lubman, et al., "What do the FDA and Pharma Companies Think of Toxicogenomics" (2002)
	294.	Lugovskoy et al., Cell, 99: 747-755 (1999)
	295.	Luhe, A., et al., Toxicol. Sciences, 73:315-328, (2003)
	296.	Lullmann & Lullmann-Rauch, Toxicol. Appl. Pharmacol., 61: 138-146 (1981)
	297.	MacGregor, et al., Toxicol. Sciences, 59:17-36, (2001)
	298.	Mahnke et al., Arch. Biochem. Biophys., 337: 62-68 (1997)
	299.	Mann, Toxicol. Pathol., 25: 72-79 (1997)
	300.	Manoukian & Carson, Drug Saf., 15: 64-71 (1996)
	301.	Mansfield, T., et al., Ann. Mtg. Of the Amer. College of Toxicol., p. 516
	302.	Marketing Materials, "Symposium on Toxicogenomics Launches New National Academics Program," Emerging Issues, 2:1-7, (2003)
	303.	Markovich et al., "Heavy metals mercury, cadmium, and chromium inhibit the activity if the mammalian liver and kidney sulfate transporter sat-1," Toxicol. Appl. Pharmacol. 154:181-187 (1999)
	304.	Martelli et al., J. Pharmacol. Exp. Ther., 273: 113-120 (1995)
	305.	Masubuchi et al., J. Pharmacol. Exp. Ther., 287: 208-213 (1998)
	306.	Masubuchi et al., J. Pharmacol. Exp. Ther., 292: 982-987 (2000)
	307.	Mattes, W., & Orr, M., "Concordance of Toxicogenomic Predictions and Mechanistic Analysis for compounds Tested in Both Rat Liver and Primary Rat Hepatocytes," LabFusion 2004 Presentation, (2004)
	308.	Mattes, W., et al., "Cross-Species Analysis of Phenobarbital-Induced Gene Expression Changes in Dog and Rat," Soc. Of Toxicol. Mtg. 2003, (2003) Abstract only
	309.	Mattes, W., et al., "Cross-Species Analysis of Phenobarbital-Induced Gene Expression Changes in Dog and Rat," Soc. Of Toxicol. Mtg. 2004, (2004)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	15 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	310.	Mayeux & Sano, N. Engl. J. Med., 341: 1670-1679 (1999)
	311.	Mayol et al., Carcinogenesis., 13: 2381-2388 (1992)
	312.	Maziasz et al., Toxicol. Appl. Pharmacol., 110: 365-373 (1991)
	313.	McKillop et al., Xenobiotica., 28: 465-478 (1998)
	314.	MDS Pharma Services Marketing Materials, "Pharmotif Solutions: Smart Decisions in Discovery and New Applications for Existing Drugs," 1-6, (2003)
	315.	Mendrick, D. L., ToxExpress, FDA-DIA Pharmacogenomics Workshop 5/02, (2002)
	316.	Mendrick DL, Effects of Rat Gender and Strain; pub. 168 (abstract)
	317.	Mendrick, D., "Discovery of Relevant biomarkers for Nonclinical and Clinical Applications," American College of Toxicology Mtg. 11/8/04, (2004)
	318.	Mendrick, D., "Role of Gene Expression Studies in Nonclinical Toxicogenomics," PhRMA/FDA Genomics (Microarray) Biostatistics Workshop, (2004)
	319.	Mendrick, D.L., et al., "Using Gene Markers Identified From a Large Database Built with Primary Rat Hepatocytes for Prediction of Human Hepatotoxicity," Society of Toxicology Mtg, (2002)
	320.	Mendrick, D.L., et al., Cross compound predictions and pathway analysis using gene expression profiles from acetaminophen or carbon tetrachloride, two structurally distinct liver toxicants," Society of Toxicology Mtg, (2002)
	321.	Mendrick I, Cysteine Protease Inhibitor (2004)
	322.	Mendrick, Extracellular Matrix Protein Dermatotontin., (2004)
	323.	Mendrick., Chemokine (2004)
	324.	Mendrick., Lipid Transporter (2004)
	325.	Mendrick., "General Biological Findings for 80 Genes" (2004)
	326.	Mendrick, "Genomic Search for Candidate Biomarkers" (2004)
	327.	Menegazzi et al., Hepatology, 25: 585-592 (1997)
	328.	Meneses-Lorente, et al., Chem. Res. Toxicol., 16(9):A-H, 1070-1077), (2003)
	329.	Metz & Ritter, J. Biol. Chem., 237: 5607-5614 (1998)
	330.	Metz et al., Mol. Pharmacol., 58: 319-327 (2000)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	16 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	331.	Meyer, K., et al., Carcinogenesis, 24(5):975-984, (2003)
	332.	Milam and Byard, Toxicol. Appl. Pharmacol., 79: 342-347 (1985)
	333.	Minamide et al., J. Pharm. Sci., 87: 640-646 (1998)
	334.	Mino et al., J. Histochem. Cytochem., 46: 1151-1160 (1998)
	335.	Miracle et al., The Path from Molecular Indicators of Exposure., 12 : 457-462 (2003)
	336.	Mitchell & Acosta, J. Toxicol. Environ. Health, 7: 83-92 (1981)
	337.	Mitchell et al., Ann. Intern. Med., 84: 181-192 (1976)
	338.	Monteith et al., Drug Chem. Toxicol., 19: 71-84 (1996)
	339.	Moore et al., Fundam. Appl. Toxicol., 3: 560-568 (1983)
	340.	Moran et al., Immunopharmacology, 12: 245-250 (1986)
	341.	Morgan, K.T., et al., Toxicol. Pathol., 30(4):435-451, (2002)
	342.	Morigasaki et al., Biochem. Biophys. Res. Commun., 273: 261-266 (2000)
	343.	Morooka et al., J. Biol. Chem., 270: 30084-30092 (1995)
	344.	Motoki et al., Cancer Lett., 135: 145-150 (1999)
	345.	Nakamura, et al., Clinical Immun. And Immunopath., 66(1):33-42, (1993)
	346.	Newsholme, et al., Electrophoresis, 21:2122-2128, (2000)
	347.	Nguyen et al. (2002), "Tumor classification by partial least squares using microarray gene expression data," Bioinformatics 18(1):39-50.
	348.	Nicholls-Grzemski et al., Toxicol. Sci., 56: 220-228 (2000)
	349.	Nims et al., Carcinogenesis., 8: 67-71 (1987)
	350.	Nordberg & Svensson, Drug Saf., 19: 465-480 (1998)
	351.	Nuwaisyr et al., "Microarrays and toxicology: the advent of toxicogenomics," Molecular Carcinogenesis 24(3):153 - 159, 1999.
	352.	Nuwaysir, et al., Cancer Research, 56:3704-3710, (1996)

Examiner Signature	Date Considered	
--------------------	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	17 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	353.	Oberhammer et al., Hepatology, 23: 329-337 (1996)
	354.	O'Brien, et al., Toxicol. And Appl. Pharma., 171:27-37, (2001)
	355.	Ohta et al., Biochem. J., 324: 777-782 (1997)
	356.	Olden & Guthrie, Mutation Research, 473:3-10, (2001)
	357.	Olson et al., Fundam. Appl. Toxicol., 22: 631-640 (1994)
	358.	Omiecinski et al., Mol. Pharmacol., 38: 462-470 (1990)
	359.	Omiecinski, et al., Toxicol. Sciences, 48:151-156, (1999)
	360.	Omogbai et al., Drug Chem. Toxicol., 22: 629-242 (1999)
	361.	Ono et al., Biol. Pharm. Bull., 18: 1779-1783 (1995) Abstract only
	362.	Ono et al., Chem. Pharm. Bull. (Tokyo), 43: 1492-1496 (1995)
	363.	Orr, M., et al., "Concordance of Toxicogenomic Predictions and Mechanistic Analysis for Compounds Tested in Both Rat Liver and Primary Rat Hepatocytes, Soc. Of Toxicol. Mtg., (2004)
	364.	Orr, M., et al., "Cross-species Comparisons - Human and Rat," Soc. Of Toxicol. Mtg., (2004)
	365.	Orr, M.S., et al., "Microarray Analysis of NRF2 Pathway and Novel Co-Regulated Genes Induced by Acetaminophen," Soc. Of Toxicol. Mtg., (2002)
	366.	Orr, M.S., et al., "Predicting Toxicity in Two distinct Sections of the Kidney via Microarray Analysis," Soc. Of Toxicol. Mtg., (2002)
	367.	Orr, M, et al. "Challenges and Limitations of Gene Expression Profiling" 60: 6-10 (2001)
	368.	Orr, Michael, "Comparison of Liver Gene Dysregulation" 21: 253-262 (2002)
	369.	Orsler et at., Toxicol. Sci., 47: 203-210 (1999)
	370.	Outinen et al., Blood, 94: 959-967 (1999)
	371.	Owen et al., Biochem. J., 348 Pt 3: 607-614 (2000)
	372.	Panduro et al., Nephron, 65: 100-107 (1993)
	373.	Park & Pirmohamed, Toxicol. Lett., 120: 281-291 (2001)
	374.	Park et al., Pharmacol. Ther., 68: 385-424 (1995)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	18 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	375.	Passreiter et al., J. Cell Biol., 141: 373-383 (1998)
	376.	Peng et al., JBC 271(6): 3324-3327 (1996).
	377.	Pennie & Kimber, Toxicology in Vitro, 16:319-326, (2002)
	378.	Pennie, et al., Toxicol. Lett., 120: 353-358 (2001)
	379.	Pennie, et al., Toxicol. Sci. 54: 277-283 (2000)
	380.	Pennie, Toxicol. Lett., 112-113: 473-477 (2000)
	381.	Perrone et al., Toxicol. Appl. Pharmacol., 150: 277-286 (1998)
	382.	Petricoin III, et al., Nature Genetics Supp., 32:474-479, (2002)
	383.	Pfeffer et al., J Immunology 153(4):1789-1797 (1994)
	384.	Pischedda et al., Proc. Natl. Acad. Sci. U.S.A., 92: 3511-3515 (1995)
	385.	Plant, N., et al., Toxicol. And Applied Pharma., 183:127-134, (2002)
	386.	Pohl et al., Arthritis Rheum., 37: 1557 (1994)
	387.	Pollenz et al., Toxicol. Sci., 42: 117-128 (1998)
	388.	Porter, M., et al., " Determination of Biological Replicate Number for Rat and Human Microarray-Based Predictive and Mechanistic Assays," Soc. Of Toxicol. Mtg., (2003) Abstract only
	389.	Porter, M., et al., "Effects of Hydration, Fasting, and Anesthesia on Baseline Gene Expression," Soc. Of Toxicol. Mtg., (2003) Abstract only
	390.	Porter, M., et al., "Liver Effects at the Gene Expression Level of Food-Tasting, Water Deprivation, and Anesthetic Agent Administration in Untreated Rats," Soc. Of Toxicol. Mtg., (2003) Abstract only
	391.	Porter, M.W., et al., "Comparison of Microarray Data Generated from the Same RNA at 19 Different Processing Sites," Soc. Of Toxicol. Mtg., (2002)
	392.	Porter, Mark, "Comparison of Microarray data Generated from the same RNA at 15 Different Processing Sites," Soc. Of Toxicol. Mtg. 10/03, (2003) Abstract only
	393.	Poyet & Labrie, Mol. Cell. Endocrinol., 42: 283-288 (1985)
	394.	Prevot et al. J. Biol. Chem., 276: 9640-9648 (2001)
	395.	Pumford et al., Drug Metab. Rev., 29: 39-57 (1997)
	396.	Raats, et al., Am. J. Pathol. 156:1749-1765, (2000)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	19 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	397.	Raburn et al., "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," Endocrinology 136(12):5769 - 5777, 1995.
	398.	Raburn et al., Endocrinology 136(12):5769-5777, 1995. Abstract only
	399.	Rajeski, David, "Exploring the Genomics Frontier," Risk Policy Report, pp. 1-5, (2002)
	400.	Ratanasavanh et al., Xenobiotica., 18: 765-771 (1988)
	401.	Ray & Jena, Arch. Toxicol., 73: 594-606 (2000)
	402.	Raychaudhuri et al., "Basic microarray analysis: grouping and feature reduction," Trends Biotechnol. 19:189-193 (2001)
	403.	Raymond et al., J. Toxicol. Environ. Health, 51: 463-476 (1997)
	404.	Reilly et al., Biochem. Biophys. Res. Commun., 282: 321-328 (2001)
	405.	Rejeski D., Exploring the Genomics Frontier, August 20, 2002
	406.	Reuter et al., Life Sci., 55: 1-8 (1994)
	407.	Rice et al., Carcinogenesis., 15: 395-402 (1994)
	408.	Rich et al., Nature, 407: 777-783 (2000)
	409.	Richert, L., et al., Toxicol. And Appl. Pharmacol., 191:130-146, (2003)
	410.	Riekkinen et al., Eur. J. Pharmacol., 322: 1-9 (1997)
	411.	Riekkinen et al., Eur. J. Pharmacol., 323: 11-19 (1997)
	412.	Riendeau et al., Br. J. Pharmacol., 121: 105-117 (1997)
	413.	Rininger et al., Biochem. Pharmacol., 52: 1749-1755 (1996)
	414.	Rininger et al., Drug Discov. Today, 5: 560-568 (2000)
	415.	Roberts et al., Toxicol. Appl. Pharmacol., 135: 192-199 (1995)
	416.	Rockett & Dix, Environ. Health Perspect., 107: 681-685 (1999)
	417.	Rodi et al., Toxicol. Pathol., 27: 107-110 (1999) Abstract only
	418.	Rodrigues & Machinist, Toxicol. Appl. Pharmacol., 137: 193-201 (1996)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	20 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	419.	Ronchetti et al., "Robust Linear Model Selection by Cross-Validation," J. Am. Statistical Assoc. 92:1017-1023 (1997)
	420.	Ruepp et al., Toxicol. Sci., 65: 135-150 (2002)
	421.	Runge-Morris et al., Drug Metab. Dispos., 26: 795-801 (1998)
	422.	Rusyn, et al., Cancer Research, 64:1050-1057. (2004)
	423.	Sachidanandam et al., Nature, 409: 928-933 (2001)
	424.	Safe, Annu. Rev. Pharmacol. Toxicol., 38: 121-158 (1998)
	425.	Salter and Nilsson, Drug Disc. and Dev., 6(1):117-122 (2003)
	426.	Sanz, et al., British J. of Cancer, 75(4):487-492, (1997)
	427.	Scales & Timbrell, J. Toxicol. Environ. Health, 10: 941-953 (1982)
	428.	Scali et al., Pharmacol. Res., 36: 463-469 (1997)
	429.	Scassa et al., Exp. Cell Res., 244: 460-469 (1998) Abstract only
	430.	Schiaffonati & Tiberio, Liver, 17: 183-191 (1997) Abstract only
	431.	Schiller et al., Toxicol. Appl. Pharmacol., 81: 356-361 (1985)
	432.	Schilter, B. et al. Activation of cytochrome P450 gene expression in rat brain by phenobarbital-like inducers. J Pharmacol Exp Ther 294(3):916-22 (Sept. 2000). Abstract only.
	433.	Schiodt et al., N. Engl. J. Med., 337: 1112-1117 (1997)
	434.	Scholer et al., Am. J. Med., 80: 34-38 (1986)
	435.	Schulte-Hermann et al., Cancer Res., 48: 2462-2468 (1988)
	436.	Schuppe-Koistinen, et al., Toxicology, 179:197-219, (2002)
	437.	Seefeld et al., Arch. Environ. Contam. Toxicol., 9: 317-327 (1980)
	438.	Sendo et al., Chem. Pharm. Bull. (Tokyo), 32: 795-796 (1984)
	439.	Servais & Galand, Cell Biol. Int Rep., 16: 319-328 (1992)
	440.	Shankar, K., et al., "PPAR-a Mediates Diabetes-Induced Resistance Against Acetaminophen Hepatotoxicity: . . .," Ann. Mtg. Of the Amer. College of Toxicol., p.526 (2002) Abstract only

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box ➡ +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	21 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	441.	Shannon et al., J. Pharmacol. Exp. Ther., 255: 1071-1077 (1990)
	442.	Shao, "Linear Model Selection by Cross-Validation," J. Am. Statistical Assoc. 88:486-494 (1993)
	443.	Shervington, Biochem. Mol. Biol. Int., 45: 303-313 (1998) Abstract only
	444.	Shiota et al., Res. Commun. Mol. Pathol. Pharmacol., 94: 141-146 (1996)
	445.	Shultz et al., Toxicol. Appl. Pharmacol., 154: 84-96 (1999) Abstract only
	446.	Sidhu & Omiecinski, J. Biochem. Mol. Toxicol., 13: 1-9 (1999) Abstract only
	447.	Sidhu & Omiecinski, J. Biol. Chem., 273: 4769-4775 (1998) Abstract only
	448.	Sidhu et al., Arch. Biochem. Biophys., 301: 103-113 (1993)
	449.	Simmons, P.T. & Portier, C.J., Carcinogenesis, 23(6):903-905, (2002)
	450.	Sinz & Woolf, Biochem. Pharmacol., 54: 425-427 (1997)
	451.	Skouteris and McMenamin, Biochem. J., 281: 729-733 (1992)
	452.	Skrtic et al., J. Hepatol., 27: 903-911 (1997)
	453.	Smith, Trends Pharmacol. Sci., 22: 281-285 (2001)
	454.	Snape et al., Neuropharmacology, 38: 181-193 (1999)
	455.	Soffers, A.E.M.F., et al., Toxic. In Vitro, 15:539-551 (2001)
	456.	Somani & Dube, Int. J. Clin. Pharmacol. Ther. Toxicol., 27: 367-387 (1989)
	457.	Somani, Biopharm. Drug Dispos., 10: 187-203 (1989)
	458.	Soni et al., Regul. Toxicol. Pharmacol., 29: 165-174 (1999)
	459.	Sprinkle, C., et al., Cancer Letters, 101:97-106, (1996)
	460.	Stachlewitz et al., J. Pharmacol. Exp. Ther., 282: 1591-1599 (1997)
	461.	Steiner, et al., Environ. Health Perspect., 112(12):1236-1248, (2004)
	462.	Stohs et al., Biochem. Biophys. Res. Commun., 111:854-859 (1983)

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box →

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	22 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	463.	Su, et al., Proc. Natl. Acad. Sci. USA, 99(17):11181-11186, (2002)
	464.	Sœurmen & Eryëurek, Toxicology, 75: 63-69 (1992) Abstract only
	465.	Suter, et al., "Toxicogenomics: Correlation of acetaminophen-induced hepatotoxicity with gene expression using DNA microarrays," Soc. Of Toxicogenomics Mtg., (2000)
	466.	Sutter, et al., Mol. Cancer Therapeutics, 1:1283-1292, (2002)
	467.	Suzuki and Sudo, Japan J. Pharmacol., 49:43-51, (1989)
	468.	Tamura et al., Toxicology, 63: 199-213 (1996) Abstract only
	469.	Tao, et al., Experimental Hermatology, 31:251-260 (2003)
	470.	Tarloff et al., Fundam. Appl. Toxicol., 30: 13-22 (1996)
	471.	Tenniswood et al., Mol. Cell. Endocrinol., 37: 153-158 (1984)
	472.	Thomas, R.S., et al., Molecular Pharmacol., 60(6):1189-1194, (2001)
	473.	Timbrell et al., J. Pharmacol. Exp. Ther., 213: 364-369 (1980)
	474.	Timbrell et al., J. Toxicol. Environ. Health, 10: 955-968 (1982)
	475.	Timbrell, Arch. Toxicol. Suppl., 2: 1-8 (1979)
	476.	Tournier et al., Lab. Invest., 59: 657-665 (1988)
	477.	Trauner et al., N. Engl. J. Med., 339: 1217-1227 (1998)
	478.	Tu, Y., et al., Proc. Nat'l Acad. Sci. USA, 99(22):14031-14036, (2002)
	479.	Tucker et al., Fundam. Appl. Toxicol., 3: 579-586 (1983)
	480.	Tucker, Am. J. Med., 73: 27-30 (1982)
	481.	Tygstrup et al., J. Hepatol., 25: 183-190 (1996)
	482.	Tygstrup et al., J. Hepatol., 27: 156-162 (1997)
	483.	Tygstrup, et al., Biochem. And Biophys. Res. Commun., 290(1):518-525, (2002)
	484.	Uhl et al., Mutat. Res., 468: 213-225 (2000) Abstract only

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box ➔ +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	23 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	485.	van Gijssel et al., Carcinogenesis, 18: 1027-1033 (1997)
	486.	Vance et al., Epilepsia, 35: 1016-1022 (1994)
	487.	Verstrepen, et al., Kidney Int'l, 43:1267-1279, (1993)
	488.	Venturelli et al., Overexpression of DR-nm23, 92: 7435-7439 (1995)
	489.	Visen et al., J. Pharmacol. Toxicol. Methods, 40: 173-179 (1998)
	490.	Wan et al., Infect. Immun., 63: 2435-2442 (1995)
	491.	Wang & Dickinson, Drug Metab. Dispos., 26: 98-104 (1998)
	492.	Waring & Ulrich, Annu. Rev. Pharmacol. Toxicol., 40: 335-352 (2000)
	493.	Waring et al., Toxicol. Appl. Pharmacol., 175: 28-42 (2001)
	494.	Waring et al., Toxicol. Lett., 120: 359-368 (2001)
	495.	Waring, et al., Environ. Health Perspect., 111:863-870, (2003)
	496.	Waterfield et al., Biochem. Pharmacol., 46: 589-595 (1993)
	497.	Weber et al., Fundam. Appl. Toxicol., 21: 523-534 (1993)
	498.	Weber et al., Toxicology, 66: 133-144 (1991)
	499.	Weisenberg-Boettcher et al., A Novelty Highly Potent, 11/12: 501-509 (1989)
	500.	Wessely, S., et al., Human & Experimental Toxicology, 18:740-764, (1999)
	501.	White et al., Biochem. Pharmacol., 45: 21-30 (1993)
	502.	White et al., Carcinogenesis, 13: 2197-2203 (1992)
	503.	Wilson, et al. PNAS 96:12833-12838 (1999)
	504.	Woodcroft & Novak, Drug Metab. Dispos., 26: 372-378 (1998) Abstract only
	505.	Woodward & Timbrell, Toxicology, 30: 65-74 (1984)
	506.	Woolf et al., Drug Metab. Dispos., 21: 874-882 (1993)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Please type a plus sign (+) inside this box → +

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/541,937
		Filing Date	07/10/06
		First Named Inventor	MENDRICK
		Group Art Unit	1635
		Examiner Name	Unassigned
Sheet	24 of 24	Attorney Docket Number	GENE-078/06US

OTHER – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	507.	Xiong et al., "Feature (Gene) Selection in Gene Expression-Based Tumor Classification," Mol. Genet. Metab. 73:239-247 (2001)
	508.	Xiong et al., Life Sci., 65: 421-430 (1999)
	509.	Xu, et al., World J. Gastroenterol, 10(2):250-254, (2004)
	510.	Yamada et al., Life Sci., 61: 171-179 (1997) Abstract only
	511.	Yamaki et al., "Cellular mechanism of lithiumk-induced nephrogenic diabetes insipidus in rats," Am. J. Physiol. Renal Physiol. 261:F505-F511, (1991)
	512.	Yang et al., Am J Physiology 277(1):F10-F16 (1999)
	513.	Yata et al., J. Hepatol., 30: 419-424 (1999)
	514.	Zarif et al., The Effect of A Selective 5-Lipoxygenase, Vol. 20, 217-227 (1996)
	515.	Zeeberg, et al., Genome biology, 4:R28:1-8, (2003)
	516.	Zhao Y. et al, Activation of Pro-death Bel-2 Family, Vol. 276: 27432-27440 (2001)
	517.	Zhou G., et al, Role of AMP-activated protein kinase in mechanism, 108: 1167-1174

47506 v1/DC

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Unique citation designation number (optional). ²See attached Kinds of U.S. Patent Documents. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.